

CLAIMS

What is claimed is:

Claim 1. A biopolymer marker comprising the sequence (R)HYGETKMNQRSSR(S) or an analyte thereof useful in indicating at least one particular disease state.

Claim 2. The biopolymer marker of claim 1 wherein said disease state is predictive of Alzheimers disease.

Claim 3. A method for evidencing and categorizing at least one disease state comprising:

obtaining a sample from a patient;
conducting mass spectrometric analysis on said sample;
evidencing and categorizing at least one biopolymer marker sequence or analyte thereof isolated from said sample; and,
comparing said at least one isolated biopolymer marker sequence or analyte thereof to the biopolymer marker sequence as set forth in claim 1;
wherein correlation of said isolated biopolymer marker and said biopolymer marker sequence as set forth in claim 1 evidences and categorizes said at least one

1 disease state.

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3 Claim 4. The method of claim 3, wherein said step
4 of evidencing and categorizing is particularly directed to
5 biopolymer markers or analytes thereof linked to at least
6 one risk of disease development of said patient.

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8 Claim 5. The method of claim 3, wherein said step
9 of evidencing and categorizing is particularly directed to
10 biopolymer markers or analytes thereof related to the
11 existence of a particular disease state.

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13 Claim 6. The method of claim 3, wherein the sample
14 is an unfractionated body fluid or a tissue sample.

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17 Claim 7. The method of claim 3, wherein said sample
18 is at least one of the group consisting of blood, blood
19 products, urine, saliva, cerebrospinal fluid, and lymph.

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21 Claim 8. The method of claim 3, wherein said mass
22 spectrometric analysis is selected from the group
23 consisting of Surface Enhanced Laser Desorption Ionization
24 (SELDI) mass spectrometry (MS), Maldi Qq TOF, MS/MS,

1 TOF-TOF, and ESI-Q-TOF or an ION-TRAP.

2
3 Claim 9. The method of claim 3, wherein said
4 patient is a human.

5
6 Claim 10. A diagnostic assay kit for determining
7 the presence of the biopolymer marker or analyte thereof
8 of claim 1 comprising:

9 at least one biochemical material which is capable of
10 specifically binding with a biomolecule which includes at
11 least said biopolymer marker or analyte thereof, and
12 means for determining binding between said
13 biochemical material and said biomolecule;

14 whereby at least one analysis to determine a presence
15 of a marker, analyte thereof, or a biochemical material
16 specific thereto, is carried out on a sample.

17
18 Claim 11. The diagnostic assay kit of claim 10,
19 wherein said biochemical material or biomolecule is
20 immobilized on a solid support.

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22 Claim 12. The diagnostic assay kit of claim 10
23 including:

24 at least one labeled biochemical material.

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1 Claim 13. The diagnostic assay kit of claim 10,
2 wherein said biochemical material is an antibody.

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4 Claim 14. The diagnostic assay kit of claim 12,
5 wherein said labeled biochemical material is an antibody.

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7 Claim 15. The diagnostic assay kit of claim 10,
8 wherein the sample is an unfractionated body fluid or a
9 tissue sample.

10
11 Claim 16. The diagnostic assay kit of claim 10,
12 wherein said sample is at least one of the group
13 consisting of blood, blood products, urine, saliva,
14 cerebrospinal fluid, and lymph.

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16 Claim 17. The diagnostic assay kit of claim 10,
17 wherein said biochemical material is at least one
18 monoclonal antibody specific therefore.

19
20 Claim 18. A kit for diagnosing, determining risk-
21 assessment, and identifying therapeutic avenues related to
22 a disease state comprising:

23 at least one biochemical material which is capable of
24 specifically binding with a biomolecule which includes at

1 least one biopolymer marker including the sequence
2 (R)HYGETKMNQRSSR(S) or an analyte thereof related to said
3 disease state; and
4 means for determining binding between said
5 biochemical material and said biomolecule;
6 whereby at least one analysis to determine a presence
7 of a marker, analyte thereof, or a biochemical material
8 specific thereto, is carried out on a sample.

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10 Claim 19. The kit of claim 18, wherein said
11 biochemical material or biomolecule is immobilized on a
12 solid support.

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14 Claim 20. The kit of claim 18 including:
15 at least one labeled biochemical material.

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17 Claim 21. The kit of claim 18, wherein said
18 biochemical material is an antibody.

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20 Claim 22. The kit of claim 20, wherein said labeled
21 biochemical material is an antibody.

22
23 Claim 23. The kit of claim 18, wherein the sample is
24 an unfractionated body fluid or a tissue sample.

1 Claim 24. The kit of claim 18, wherein said sample
2 is at least one of the group consisting of blood, blood
3 products, urine, saliva, cerebrospinal fluid, and lymph.
4

5 Claim 25. The kit of claim 18, wherein said
6 biochemical material is at least one monoclonal antibody
7 specific therefore.
8

9 Claim 26. The kit of claim 18, wherein said
10 diagnosing, determining risk assessment, and identifying
11 therapeutic avenues is carried out on a single sample.
12

13 Claim 27. The kit of claim 18, wherein said
14 diagnosing, determining risk assessment, and identifying
15 therapeutic avenues is carried out on multiple samples
16 such that at least one analysis is carried out on a first
17 sample and at least another analysis is carried out on a
18 second sample.
19

20 Claim 28. The kit of claim 27, wherein said first
21 and second samples are obtained at different time periods.
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23 Claim 29. Polyclonal antibodies produced against a
24 marker sequence ID including the sequence

1 (R)HYGETKMNQRSSR(S) or an analyte thereof in at least one
2 animal host.

3
4 Claim 30. An antibody that specifically binds a
5 biopolymer including a marker consisting of the sequence
6 (R)HYGETKMNQRSSR(S) or at least one analyte thereof.

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8 Claim 31. The antibody of claim 30 that is a
9 monoclonal antibody.

10
11 Claim 32. The antibody of claim 30 that is a
12 polyclonal antibody.

13
14 Claim 33. A process for identifying therapeutic
15 avenues related to a disease state comprising:

16 conducting an analysis as provided by the kit of
17 claim 18; and

18 interacting with a biopolymer consisting of the
19 sequence (R)HYGETKMNQRSSR(S) or at least one analyte
20 thereof;

21 whereby therapeutic avenues are developed.

22
23 Claim 34. The process for identifying therapeutic
24 avenues related to a disease state in accordance with

1 claim 33, wherein said therapeutic avenues regulate the
2 presence or absence of the biopolymer consisting of the
3 sequence (R)HYGETKMNQRSSR(S) or at least one analyte
4 thereof.

5
6 Claim 35. The process for identifying therapeutic
7 avenues related to a disease state in accordance with
8 claim 33, wherein said therapeutic avenues developed
9 include at least one avenue selected from a group
10 consisting of 1)utilization and recognition of said
11 biopolymer markers, variants or moieties thereof as direct
12 therapeutic modalities, either alone or in conjunction
13 with an effective amount of a pharmaceutically effective
14 carrier; 2)validation of therapeutic modalities or disease
15 preventative agents as a function of biopolymer marker
16 presence or concentration; 3)treatment or prevention of a
17 disease state by formation of disease intervention
18 modalities; 4)use of biopolymer markers or moieties
19 thereof as a means of elucidating therapeutically viable
20 agents, 5)instigation of a therapeutic immunological
21 response; and 6) synthesis of molecular structures related
22 to said biopolymer markers, moieties or variants thereof
23 which are constructed and arranged to therapeutically
24 intervene in said disease state.

1 Claim 36. The process for identifying therapeutic
2 avenues related to a disease state in accordance with
3 claim 35, wherein said treatment or prevention of a
4 disease state by formation of disease intervention
5 modalities is the formation of biopolymer/ligand
6 conjugates which intervene at receptor sites to prevent,
7 delay or reverse a disease process.

8
9 Claim 37. The process for identifying therapeutic
10 avenues related to a disease state in accordance with
11 claim 35, wherein said means of elucidating
12 therapeutically viable agents includes use of a
13 bacteriophage peptide display library or a bacteriophage
14 antibody library.

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16 Claim 38. A process for regulating a disease state
17 by controlling the presence or absence of a biopolymer
18 selected from the group consisting of the sequence
19 (R)HYGETKMNQRSSR(S) or at least one analyte thereof.
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